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IS 13009 (2000): Contraceptive Devices - Tubal Ring [MHD 3: Obstetric and Gynaecological Instruments and Appliances]

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(पहला पुनरीक्षण)

Indian Standard

CONTRACEPTIVE DEVICES — TUBAL RING — SPECIFICATION

(First Revision)

ICS 11.200

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

April 2000

Price Group 3

Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD 3

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Obstetric and Gynaecological Instruments and Appliances Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

Plastics, rubber, other polymers, metals, etc, are being increasingly used in various medical devices. Different materials used are covered under these broad categories. However, it is imperative to ensure that the raw material used in the manufacture of medical devices is free from any harmful effect on the body either on its own or in combination with others, or after interaction with body tissues and fluids. It shall, therefore, be the responsibility of the manufacturers of a medical device to satisfy themselves of the biological compatibility of the materials used without causing undue allergic, toxic or inflammatory reaction in the human body. Materials used shall also be capable of withstanding prescribed sterilization process without any deterioration or effect.

This standard was first published in 1990 at the instance of Ministry of Health and Family Welfare, Government of India. The present revision has been necessitated as a result of experience gained through its implementation by the Ministry of Health. This has also taken into consideration the difficulties faced by the Indian manufacturers either at the manufacturing or at the testing stage. Problems faced by the Gynaecologists while using this device have also been kept in mind.

Specific guidelines for good manufacturing practices relating to contraceptive devices do not exist at present. Manufacturers should follow the guidelines provided by their collaborators or their own for Good Manufacturing Practices, for manufacturing these devices till the guidelines are formulated.

This device would be required to undergo extractables and implantation tests on animals and clinical trials on voluntary acceptors. This device has been declared as 'drug' by the Minsitry of Health and Family Welfare (Department of Health) under the ***Drugs and Cosmetics Act, 1940.*** Since the regulatory functions for ensuring conformity to this standard rest with the Drugs Controller General (India), BIS Certification Marking would not be applicable for this device.

There is no ISO/ IEC standard on the subject. In the formulation of this standard, assistance has been derived from IITD MDS.02 'Standard for Tubal Ring' prepared by the Indian Institute of Technology, New Delhi.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values ***(revised)***'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

CONTRACEPTIVE DEVICES — TUBAL RING — SPECIFICATION

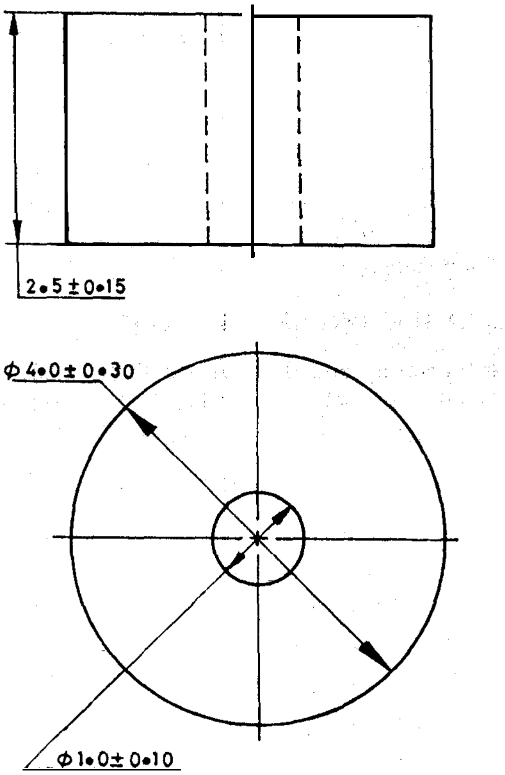
(*First Revision*)

1 SCOPE

1.1 This standard specifies the dimensions and other requirements of tubal ring, a tubal ligation device.

2 SHAPE AND DIMENSIONS

The shape and dimensions of tubal ring shall be as shown in Fig. 1.



All dimensions in millimetres.

FIG. 1 TUBAL RING

3 MATERIAL

The tubal rings shall be made from silicone rubber of medical grade which shall pass the extractables test according to the method given in Annex A and implantation test as given in Annex B.

4 REQUIREMENTS

4.1 The tubal rings shall be cut at right angle (maximum 5° angulation allowed) and shall be round without any fibrous protrusions at the outer and inner surfaces.

4.2 The silicone rubber tube of which the tubal ring is made shall not degrade by prolonged exposure to the biological environment or by procedure of sterilization, shall be sufficiently resistant to unintended influence by the body fluids and tissues and shall be biologically compatible without causing allergic, toxic or inflammatory reaction.

4.3 Tubal ring when loaded on the fallopian tube shall produce an acceptable level of efficacy and minimal incidence of adverse reactions.

4.4 The tubal ring shall be radio-opaque.

4.5 The tubal ring shall meet the requirements for stress properties as given in **5.1** and 5.2. When loaded on the fallopian tube the tubal ring shall have necessary memory for its inner diameter as per requirement given in 5.3 to compress the fallopian tube.

4.6 The tubal ring shall be stored at a temperature ranging from 0 to 50°C.

5 TESTS

5.0 All the tests on the tubal ring shall be carried out on the final product after sterilization.

5.1 Fracture Test

5.1.0 This test is used to determine the load at fracture (maximum load) during fracture test and elongation at maximum load. From the value of elongation at maximum load strain capacity is also calculated. This test shall be done very stringently.

5.1.1 The test is performed on a tensile testing machine with special adapters to hold two 'U' shaped steel clips of 1.35±.01 mm diameter. The crosshead separation speed is kept at 100 mm per minute.

5.1.2 To test the ring, position the tubal ring on two 'U' shaped steel grips and insert these grips into two adapter tubes, one attached to the fixed crosshead and other to the moving crosshead. The jaws are now separated and the load is measured with the help of a load cell and the values for load and displacement are recorded on a chart recorder. The strain capacity is calculated as follows;

$$\text{Strain capacity (percent)} = \frac{ED-5.5}{5.5} \times 100$$

where ED is equivalent diameter which can be calculated as follows:

$$ED = \frac{2 \times DSPL + 6.94}{3.14}$$

where $DSPL$ is the separation of jaws at break.

5.1.3 The test shall be carried out on 40 pieces of tubal rings drawn as sample for a batch size up to IO 000.

5.1.4 The load required to break the ring shall be 2. I kg, minimum. The displacement at peak load shall be 560 percent, minimum. The strain capacity shall range between 20 and 80 percent. For each parameter, out of 40 rings tested, not more than one ring shall have values outside the range.

5.2 Friction Force Test

5.2.0 This test is used to determine the force required to load the tubal ring on a standard laparocator.

5.2.1 This test shall be performed on a compression testing machine. A metal disc with a tube like projection of 5.5 mm outer diameter in the centre which can hold the dilator cone is placed on the compression plate whereas an adapter which can hold the guide is attached to the moving head. The crossheads are brought closer with a speed of 100 mm/min. To test the force, the tubal ring is loaded on the dilator cone using water as lubricant and the guide is brought right at the top of the dilator cone. The jaws are now moved closer and the load is measured with the help of a compression cell.

5.2.2 The test shall be carried out on 40 pieces of tubal rings drawn as sample from a batch size up to 10 000.

5.2.3 Out of 40 rings tested, the force required to load a tubal ring shall not exceed 3.5 kgf in more than one ring.

5.3 Memory Test

5.3.0 This test determines the capacity of the tubal ring to recover the inner diameter after stretching to 5.5 mm for an extended period.

5.3.1 For this purpose, the tubal ring shall be kept loaded on a standard laparocator for a period of 30 minutes and then removed and allowed to recover its inner diameter under unstretched condition for one minute. The test shall be carried out on 40 pieces of tubal rings drawn as sample from a batch size up to IO 000.

5.3.2 The recovery of the inner diameter shall be such that the increase in the inner diameter does not exceed 25 percent of the original diameter.

5.4 Fatigue Test

5.4.0 This test determines the ability of the tubal ring to maintain its mechanical structure even after repeated loading and unloading on'the tubal ring/band applicator or equivalent jig fixture.

5.4.1 For this purpose, the ring shall be loaded on a tubal ring/band applicator or equivalent jig fixture and after keeping it loaded for 20 minutes, it is unloaded. The process of loading and unloading is repeated on the same ring for four times after a gap of one minute between each cycle. The ring is observed for cracks and breakage.

5.4.2 The test shall be carried out on ten pieces of tubal rings drawn as sample from a batch size up to IO 000.

5.4.3 The tubal ring shall neither break nor develop any crack.

5.5 Sterility

When tubal ring is supplied as sterile, it shall be capable of meeting the requirements of any suitable sterility test method specified in Indian Pharmacopoeia.

6 LABELLING AND MARKING

6.1 Printing and illustrations shall be clear, neat, legible and indelible. The label shall be free from gross particulate matter and cuttings shall be non-adherent.

6.2 Each package shall be marked with the following:

a) Identity of the source of manufacture;
b) The batch number;
c) The method, month and year of sterilization;
d) Storage directives;
e) Use before (specify month and year); and
f) Each individual package shall carry the following text:
  i) *Warning* — Sterile unless package is opened or damaged.
  ii) The tubal ring should be held on the applicator preferably for 5 minutes but in any case not more than 15 minutes.

7 SAMPLING

7.1 Lot

All the tubal rings of the same material and produced under similar conditions of manufacture shall be grouped together to constitute a lot which shall not exceed 10 000.

7.1.1 Unless otherwise agreed to between the purchaser and the supplier, the procedure given in

IS 2500 (Part I) 'Sampling inspection procedures: Part I Attribute sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection (second *revision)* shall be followed for sampling inspection.

8 PACKAGING

8.1 One pair of tubal ring shall be packed in peel open pouch/blister pack with seal width 2 mm, minimum. The pouch/ blister pack, once opened, shall not reseal.

8.2 Each -pouch/blister pack shall ensure:

a) adequate protection of the contents during normal handling, transit and storage for a period of four years;

b) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions at temperature ranging from 0 to 50°C;

c) minimal risk for contamination of the contents during removal from the pouch/ blister pack; and

d) that the pouch/blister pack once opened cannot-be resealed.

8.3 Each pouch/blister pack shall have a suitable sterilization indicator affixed on it to ensure its sterilization.

ANNEX A

(*Clause* 3.1)

EXTBACTABLES TEST

A-I To find the suitability of the tubal ring material intended for use inside the human body, the ring material has to be tested for its **extractables** from systemic injection test (intraperitoneal and intravenous) and intracutaneous test. The procedure provides for testing the reaction of living animal tissue and of normal animals to the presence of extract of the material.

A-2 APPARATUS

A-2.1 **Autoclave**

Capable of maintaining a temperature of 121° ± 0.5°C equipped with a thermometer, a pressure gauge, a vent cock, a rack adequate to accommodate the test containers above the water level and water cooling system that will allow for cooling of the test containers to about, but not below 22°C immediately following the heating cycle.

A-2.2 **Oven**

Preferably a forced circulation model that maintains operating temperatures of 50°C or 70°C within ± 1°C.

A-2.3 **Extraction Containers**

Use containers, such as ampules or screw-cap culture test tubes, of borosilicate glass. If culture test tubes are used, they shall be closed with screw caps having suitable rubber liners. The exposed surface of the rubber liner is completely protected with an inert solid disk 0.05 to 0.075 mm in thickness. A suitable disk may be fabricated from a polytetrafluoro-ethylene resin.

A-3 PREPARATION OF APPARATUS

A-3.1 Clean all glassware thoroughly with chromic acid cleansing mixture, or if necessary with hot nitric acid, followed by prolonged rinsing with water. Clean cutting devices by an appropriate method (for example successive cleaning with acetone and methylene chloride) prior to use in subdividing a specimen. Clean all other equipment by thorough scrubbing with a suitable detergent and prolonged rinsing with water.

Render the containers and devices used for extraction, and in transfer and administration of test material, sterile and dry by a suitable process.

NOTE — Ifethylene oxide is used as the sterilizing agent, allow adequate time for complete degasing.

A-3.2 Procedure

A-3.2.1 ***Preparation of Sample***

From a sample of silicone rubber tube, use a portion equivalent to a total surface area of 60 cm^2 or 4 g by mass; subdivide into pieces of approximately 5 cm in length. Remove particulate matter, such as lint and free particles by treating each subdivided sample as follows:

Transfer the subdivided sample to a clean, glass-stoppered, 100 ml graduated cylinder of Type I glass (highly resistant borosilicate glass) and add about 70 ml of water for injection. Agitate for about 30 seconds, and drain off the water, repeat this step, and dry those pieces prepared for extraction with vegetable oil in an oven at a temperature not exceeding 50°C.

NOTE Do not clean the sample pieces with a dry or wet cloth or by rinsing or washing with an organic solvent, surfactant, etc.

A-3.2.2 *Extracts*

A-3.2.2.1 Place two properly prepared samples of the silicone rubber tube to be tested in separate extraction flasks. and add to each flask 20 ml of the appropriate extracting medium. Repeat these directions for each extracting medium required for testing. Also prepare one 20 ml blank of each medium for parallel injections and comparisons. Extract by heating in an oven at 70°C for 24 hours. Allow adequate time for the liquid within the container to reach the extraction temperature.

A-3.2.2.2 Cool to about room temperature but not below 22°C, shake vigorously and decant each extract, using aseptic precautions, into a dry, sterile ‘vessel. Store the extracts at a temperature between 22°C and 30°C and do not use for tests after 24 hours. Of importance are the contact of the tube and the time and temperature during extraction, the proper cooling, agitation, and decanting process, and the aseptic handling and storage of the extract following extraction.

NOTE — No extract should be stored at any time at a temperature below 22°C.

A-4 SYSTEMIC INJECTION TEST

A-4.1 Test Animal

Use healthy, not previously used albino mice weighing between 17 g and 23 g. For each test group use only mice of the same source. Offer water and food commonly used for laboratory animals and known with respect to composition, ad *libitum*.

A-4.2 Procedure

Inject each extract of the sample and the corresponding blank, into groups of 5 mice each in the amount and by the route set forth in Table 1. Observe the animals immediately after injection, again 4 hours after injection and not earlier than 24, 48 and 72 hours, respectively, after injection. If during the observation period none of the animals treated wit&the extract of the sample show a significantly greater reaction than the animals treated with the blank, the sample meets the requirements of this test.

Table 1 Amounts and Routes and Systemic Injection of Extracts and Blanks

Extract or Blank	Dose (per kg)	Injection	
		Route	Rate (ml/second)
Sodium chloride injection	50 ml	Intravenous	0.1
I in 20 solution of alcohol in sodium chloride injection	50 ml	Intravenous	0.1
Polyethylene glycol, 400	10 g	Intraperitoneal	—
Vegetable oil	50 ml	Intraperitoneal	—

NOTES

1 Agitate each extract vigorously prior to withdrawal of each injection dose, to ensure even distribution of the extracted matter.

2 If any animal treated with the sample shows slight signs of toxicity, and not more than 1 animal shows gross symptoms of toxicity or dies, repeat the test-using groups of IO mice each. On the repeat test, the requirements of the test are met, if none of the animals treated with the sample shows a significantly greater reaction than that observed in the animals treated with the blank.

3 The extract prepared with polyethylene glycol and blank are diluted with sodium chloride injection in rates 1:4.1 v/v and 1:7.4 v/v for systemic and intracutaneous tests respectively.

A-S INTRACUTANEOUS TEST

A-S.0 This test is deiigned for the evaluation of extracts of a plastic material in rabbits.

A-5.1 Test Animal

Select healthy, thin-skinned albino rabbits not previously used for any test, whose fur can be clipped closely and whose skin is free from mechanical irritation or trauma. In handling the amimals, avoid touching the injection sites during observation period.

A-S.2 Procedure

On the day of the test, closely clip the fur on the animal’s back on both sides of the spinal column over a sufficiently large test area. Avoid mechanical irritation and trauma. Remove loose hair by means of vacuum. If necessary, swab the skin slightly with diluted alcohol, arid dry the skin prior to injection.

Inject intracutaneously 0.2 ml of each extract of the: sample at 10 sites on one side of each of two rabbits. Similarly, at five other sites on the other sides of each rabbit inject 0.2 ml of the corresponding blank. Examine the injected sites 24, 18 and 72 hours after the injection for gross evidence! of tissue reaction such as erythema, edema, and eschar. To facilitate the examination, swab the skin lightly with diluted alcohol, and clip the fur, if necessary. Rate the observation on a numerical scale for the extract of the sample and for the blank, respectively using Table 2.

A-5.2.1 The requirements of the test are met if the average for the sample is not significantly greater than that for the blank.

NOTE Agitate each extract vigorously prior to withdrawal of each injection dose, to ensure even distribution of the extracted matter.

A-5.3 If the result is doubtful, repeat the test using fresh extract in three more rabbits. The requirements of the test are met if on the repeat test the average for the extract of the sample is not significantly greater than that for the blank.

Table 2 Evaluation of Skin Reaction
(***Clause*** A-5.2)

Erythema and Eschar Formation	**Value**
No erythema	**0**
Very slight erythema (barely perceptible)	
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythma (beet-redness) to slight eschar formulation (injuries in depth)	4
Edema Formation	
No edema	**0**
Very slight edema (barely perceptible)	
Slight edema (edges of area well detined by definite raising)	2
Moderate edema (raised approx 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

ANNEX B

(Clause 3.1)

IMPLANTATION TEST

B-1 This method of test is designed to provide information on the effects of direct contact of a test material with living tissues when implanted into the paravertebral muscle of the rat/rabbit for a period of 14 days.

B-1.1 This method of test is employed for plastic materials which are intended for long term use - covering a period from a few months to permanent use - within the body tissue.

B-2 DEFINITIONS

B-2.0 For the purpose of this test the following definitions shall apply.

B-2.1 **Final Product**

Medical device in its ready-for-use state.

B-2.2 **Test Material**

The final product or sample of final product that is to be tested.

B-2.3 **Test Specimen**

The piece of test material that is implanted.

B-2.4 **implant**

The test specimen or negative control specimen that has been implanted.

B-2.5 **Implant Site**

The implant shall be planted into the paravertebral muscle on one side of the spine and not less than 2 mm and not more than 5 mm of tissue surrounding it measured from the centre of the implant.

B-2.6 Negative **Control Specimen**

A piece of material, which when implanted by the procedure described in B-4.5 produces a negative reaction (see B-4.7.1.4).

NOTE — Negative control standards available from USP-NF Reference Standards 12601, Twinbrook Parkway, Rockville, Maryland 20852 USA or **equivalent** may be used.

B-2.7 Medical Device

Any item used in medical treatment, diagnosis or contraception, not intended to have a pharmacological reaction on the **body.**

B-3 ANIMALS AND HUSBANDRY

B-3.1 Two healthy adult rats/rabbits should be selected, whose paravertebral muscles are sufficiently large in size to allow for implantation of the test and negative control specimens, as described in B-4.5.

B-3.2 The animals shall be housed individually and have free access to food and water.

B-4 TEST AND CONTROL SPECIMENS

B-4.1 Number of Specimens Required

The minimum number of specimens for implantation in each rat/rabbit shall be:

a) not less than two negative control specimens; and

b) not less than six test specimens

NOTE — It may be necessary to implant more specimens than the minimum required because of loss. for example by extrusion of implants during the 14 days test period.

B-4.2 **Sterilization and Handling of Specimens**

B-4.2.1 Test specimens for pre-sterilized devices and pre-sterilized controls shall be aseptically handled.

B-4.2.2 All other test specimens shall be sterilized and thereafter shall be aseptically handled.

B-4.2.3 All other items used for the test shall be pre-sterilized and shall be eseptically handled.

B-4.3 **Preparation of Specimen**

B-4.3.1 The ring may be implanted as it is, and the negative control material is cut into specimen of 10 mm in length.

B-4.3.2 These cut or shaped specimens shall have smooth sides to minimize mechanical trauma during implantation.

B-4.3.3 After preparing and before implanting, place each specimen in a sterile solution containing 9 g/l of sodium chloride.

B-4.4 **Test Procedure**

B-4.4.1 On the day of the test or up to 20 hours before testing, clip the fur on the back of the rat/rabbit on both sides of the spinal column close to the skin and swab the clipped area with an antiseptic solution. Remove loose hair by means of vacuum, if necessary.

B-4.4.2 Perform the test in a clean area.

B-4,4.3 Anaesthetize the rat/rabbit with a commonly used anaesthetic agent adequate enough to prevent muscular movements, such as twitching.

B-4.5 **Implanatation of Specimens**

B-4.5.1 Implant in one of the rats/rabbits four test specimens and two negative control specimens.

B-4.5.2 Each implant shall be at least 10 mm away from any other implant.

B-4.6 **Recovery of the Implant Sites**

B-4.6.1 After the implants have been in position for 14 days, sacrifice the rats/rabbits with an overdose of anaesthetic.

B-4.6.2 Place these rats/rabbits in the prone position with the legs splayed.

B-4.6.3 Carefully excise the implant sites, leaving the implant in position.

B-4.7 **Examination of Implant Sites**

B-4.7.1 Perform the microscopic examination.

B-4.7.1.1 Examine each excised implant site under normal vision or with the aid of a low magnification lens. Record the nature, extent and distribution of any tissue reaction observed.

B-4.7.1.2 If any negative control specimen evokes a reaction other than that described in B-4.7.1.4; the results for the test specimens in the rat/rabbit shall be rejected and the test repeated in another rat/rabbit.

B-4.7.1.3 If any test specimen implant site shows a negative reaction (see B-4.7.1.4) all the test specimen implant sites and the negative control implant sites shall be removed for histological examination to confirm the response.

B-4.7.1.4 A reaction shall be considered a negative reaction if there is no reaction, or there is reaction that can be attributed to experimental trauma, typically asymmetrical, non-nectrotic and non-inflammatory.

B-4.7.1.5 If more than the minimum number of test specimens or negative control specimens are implanted, all of them shall be recovered.

B-4.7.1.6 All recovered specimens shall be considered as part of the test.

B-4.7.2 Perform the histological examination.

B-4.7.2.1 Preserve the excised implant sites in formal saline.

B-4.7.2.2 Prepare sections transverse to the excised implants.

NOTES

1 Ideally, the implant should remain in place during preparation for sectioning to ensure correct orientation of the surrounding tissue, unless adverst reaction with dehydrating or defatting solvents is Likely to occur.

2 Hard implants may be removed before cutting of sections, if cutting would otherwise be difficult.

B-4.7.2.3 Stain the section with haemotoxylin and eosin.

B-4.7.2.4 Examine the histological sections microscopically and record the findings.

B-5 TEST RESULTS

B-5.1 The tissues surrounding negative control should appear normal and entirely free from haemorrhage, film or encapsulation (see B-4.7.1.4).

B-S.2 The requirements of the test are met if, in each rat/rabbit, the reaction to not more than one of the four test specimens is significantly greater than that of the negative control implant.

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Amendments are-issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards: Monthly Additions'.

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